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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,735	05/18/2000	Lieven DeVeylder	2283/301	1507

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	32

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/574,735	Applicant(s) DEVEYLDER ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5,7-11,14,17,21,24,25,27,30,36-41,43-45,47-50 and 52-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,5,7-11,14,17,21,24,25,27,30,36-41,43-45,47-50 and 52-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *28* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2003 has been entered.

Claims 12, 13, 15, 16, 18, 19, 20, 22, 23, 28, 29, 31, 42, 46, and 51 are cancelled.

Claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36-38, 43-45, 47, 49, 53, 54, 56 and 57 are newly amended.

Claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 are rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for methods of using a nucleotide sequence encoding a plant cyclin-dependent kinase inhibitor which binds a plant CDC2a cyclin-dependent kinase, does not reasonably provide enablement for methods of using a nucleotide sequence encoding a cyclin-dependent kinase inhibitor obtained from any

source which binds a CDC2a cyclin-dependent kinase obtained from any source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

In response to the previous enablement rejection, Applicants point out that the claims have been amended to recite the methods with greater specificity. Applicants also point out that they have shown that the same phenotypic characteristics result when three different *Arabidopsis* CKI genes (CKI2 (KRP2,ICK2), KPR6(CKI 6) and KPR7(CKI7)) are overexpressed in transgenic *Arabidopsis* plants. Applicants further point to the previously submitted reference of Zhou et al. (Plant Cell Reports, 2002, Vol. 20, pages 967-975), which reports the same phenotypic characteristics result upon overexpression of the *Arabidopsis* CKI genes ICK1(KRP1,CKI1) and ICK2 (KRP2, CKI2), and the *Chenopodium rubrum* CKI gene ICKCr, in transgenic *Arabidopsis* plants (reply page 11).

The Office maintains that the full scope of the claimed invention is not enabled because the claims are directed to the use of a cyclin-dependent kinase inhibitor obtained from any source that binds to a Cdc2a cyclin-dependent kinase obtained from any source, and the ability of a cyclin-dependent kinase inhibitor obtained from any source to bind a Cdc2a cyclin-dependent kinase obtained from any source and inhibit its activity is unpredictable. For example, Wang et al. teach that ICK1, a cyclin-dependent kinase inhibitor obtained from the plant *Arabidopsis* that binds the plant cyclin-dependent kinase CDC2aAt, is an effective inhibitor of plant Cdc2-like

kinases, but not of the equivalent kinases from mammalian and yeast cells (The Plant Journal, 1998, Vol. 15, No. 4, pages 501-510, Applicant's IDS, see page 503 paragraph spanning columns 1 and 2). Accordingly, obtaining the desired effects in transgenic plants would be unpredictable if one used a nucleotide sequence encoding any cyclin-dependent kinase inhibitor obtained from any source that binds to any CDC2a cyclin-dependent kinase obtained from any source, since cyclin-dependent kinase inhibitors and cyclin-dependent kinases obtained from distantly related groups of organisms may not be able to functionally interact.

Claims 2, 5, 7, 11, 14, 17, 21, 25, 27, 30, 36, 56 and 57, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "Cdc2a", as an acronym may have more than one meaning.

Claims 2, 11, 27, 37 and 45,and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "decreasing" and "decreased", which are relative terms that lack a comparative basis.

Claims 7, 14 and 38, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "increasing" and "increased", which are relative terms that lack a comparative basis.

Claims 21, 25, 43, 44 and 47, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "reducing" and "reduced", which are relative terms that lack a comparative basis.

Claims 24, 52, 53 and 54, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph as being indefinite for depending from cancelled claims.

Claim 36, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "resulting from the transgene". First, it is unclear whether "the same characteristics" result only from "the transgene", or whether "the same characteristics" result from one of "the transgene", "a plant part" or "plant cell". Second, there is insufficient antecedent basis for the limitation "the transgene" in claim 36.

Claim 36, and claims dependent thereon, remains rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "essentially the same characteristics", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

Applicant argues that amendment of the claim to recite "essentially the same characteristics resulting from the transgene" should overcome the rejection (reply page 12).

The amendment of claim 36 does not overcome the rejection, as there is insufficient antecedent basis for the limitation "the transgene" in claim 36. Accordingly, it is unclear what transgene and what characteristics of the transgenic plant are being referred to.

Claim 39, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "altered". It is unclear in what way leaf size is altered, as leaf size may be altered in more than one way, such as an increase in thickness or thinness, an increase or decrease in surface area, etc. Additionally, "altered" is also a relative term that lacks a comparative basis.

Claim 54, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "comprises the consensus amino acid sequence as set forth in any one of SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38 or SEQ ID NO:39". It is unclear how the claimed method could be performed using a CKI comprising only one of the consensus amino acid sequence as set forth in any one of SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38 or SEQ ID NO:39, as the specification indicates that two of the consensus amino acid sequences (SEQ ID NO:34 and SEQ ID NO:35) conserved among plant and animal CKIs are essential for binding CDC2a.

Claim 56 and 57, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "comprising the CKI which binds CDC2a that was introduced into the parent plant". It is unclear whether the CKI or CDC2a was

introduced into the parent plant. The language of the claims suggests that CDC2a was introduced into the parent plant, but the disclosure teaches the introduction of a nucleic acid molecule encoding a CKI into the parent plant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 36-41, 43-45, 47-50 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. Patent No. 5,550,038 issued August 27, 1996) in view of Toyoshima et al. (Cell, 1994, Vol. 78, No. 1, pages 67-74).

The claims are drawn to a transgenic plant comprising and expressing a nucleic acid molecule encoding a cyclin-dependent kinase inhibitor which binds CDC2a and which comprises the consensus amino acid sequence as set forth in any one of SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38 or SEQ ID NO:39, and methods of expressing said nucleic acid molecule in plants.

Goodman et al. teach the expression in plants of nucleic acid molecules encoding mammalian peptides, and the desirability of expressing mammalian peptides in plant systems (column 10 claims 1-5; column 1 lines 11-49).

Goodman et al. do not teach the expression in plants of a nucleic acid molecule encoding a cyclin-dependent kinase inhibitor which binds CDC2a and which comprises the consensus

amino acid sequence as set forth in any one of SEQ ID NO:34, SEQ ID NO:35, SEQ ID NO:36, SEQ ID NO:37, SEQ ID NO:38 or SEQ ID NO:39.

Toyoshima et al. teach a nucleic acid molecule encoding a murine p27 mammalian cyclin-dependent kinase inhibitor which binds CDC2a and which comprises the consensus amino acid sequence as set forth in SEQ ID NO:34 or SEQ ID NO:35 (page 68 Figure 1; page 69 Figure 3; page 70 Figure 4).

Given the success of Goodman et al. in expressing in plants nucleic acid molecules encoding mammalian peptides, and given the desirability of expressing mammalian peptides in plant systems, it would have been prima facie obvious at the time the invention was made to express in a plant a mammalian peptide such as the murine p27 cyclin-dependent kinase inhibitor taught by Toyoshima et al., for the purpose of producing as physiologically active protein, without any surprising or unexpected results. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 13-19, 21-23, 43-48 and 51-52 of copending Application No. 09/526597. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 9, 13-19, 21-23, 43-48 and 51-52 of copending Application No. 09/526597 are directed to transgenic plants and plant cells comprising an isolated DNA sequence encoding the *Arabidopsis* cyclin-dependent kinase inhibitor CKI2 (KRP2, ICK2) which binds the Arabidopsis cyclin-dependent kinase CDC2aAt, and to methods of making said transgenic plants and plant cells, whereas claims 2, 5, 7-11, 14, 17, 21, 24-25, 27, 30, 36-41, 43-45, 47-50 and 52-57 of the instant application are directed to transgenic plants comprising a nucleotide sequence encoding a cyclin-dependent kinase inhibitor which binds CDC2a, and methods of transforming transgenic plants with said nucleotide sequence.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 16, 2003

PHUONG T. BUI
PRIMARY EXAMINER 6/16/03